



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner Lyle A. Alexander
ART UNIT 1743

In re application of
E. Alan Bates et al.
Application No. 08/935,629
Filed 09/23/97
For ASSAYING DEVICE

- - - - - CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper or fee referred to as being attached or enclosed) is being deposited with the U.S. Postal Service in an envelope with sufficient postage as first class mail addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

12 - 5 - 03

Signed: Daniel A. Sullivan Jr.

Typed Name: Daniel A. Sullivan, Jr.

Date of Signature: 12 - 5 - 03

- - - - - APPELLANT'S BRIEF

Commissioner for Patents
Alexandria, VA

(1) REAL PARTY IN INTEREST

The real party in interest is DTx, Inc., a Delaware corporation.

(2) RELATED APPEALS AND INTERFERENCES

There are no pending appeals or interferences known to appellant or the appellant's legal representative, which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

RECEIVED
DEC 15 2003
TC 1700

(3) STATUS OF CLAIMS

Claims 1, 8 and 23-48 are pending, rejected and appealed.

(4) STATUS OF AMENDMENTS

One amendment was filed subsequent to the final rejection of 12/05/02. Such amendment is entitled AMENDMENT UNDER 37 CFR §1.116. It was filed 7/03/03 and entered per USPTO communication mailed 7/22/2003 for purposes of Appeal.

(5) SUMMARY OF INVENTION

All Fig. and page references in this section are to the Figs. and specification pages of this application. A copy of the specification with line numbers is attached as Appendix II for the convenience of the Board. Locations of text inserted by amendment are indicated by the circled numbers 1-4 on page 3 and the corresponding insertions are presented on the page at the end of Appendix II. Two amendments of numerals are indicated in lines 10 and 11 of page 4. A copy of the drawings as amended is attached as Appendix III.

With reference first to Fig. 1, and as explained at page 3, lines 16-19, an assaying or drug screening device of the invention includes a cartridge/cassette 1 having a broad, lateral face 1a, a narrow, lateral face 1b, and a narrow end face 1c. Window 2 permits viewing test results on a test strip 3. Well/opening 4, situated on the broad lateral face 1a, has a top in the area of its top edge 4a. As drawn in Fig. 1, one can see that the

well/opening 4 extends from its top at edge 4a into the cartridge/cassette to surround an empty space 4b for reception of sample.

Fig. 1 in exploded view and Fig. 2 in assembled view illustrate the relationship of cap/cover 5 with cartridge/cassette 1. This relationship is explained at page 3, lines 18-25, as amended. After sample has been dropped into well/opening 4, using a pipette for instance, cap/cover 5 is put in place, as shown in Fig. 2, to seal the top of the well/opening. Space 4b becomes a chamber for retention of sample. The cap/cover 5 passes around or encircles the cartridge/cassette at 5a (Fig. 2), to constrain the cap/cover in a fluid tight relationship against the top of the well/opening. In this sealing, wall 5' of cap/cover 5 faces the broad, lateral face 1a containing the well/opening 4 and contacts the top of the well/opening.

Fig. 3, as explained at page 4, lines 1-4, shows an embodiment in which the cartridge/cassette 1 has two windows 2, two test strips 3, and two well/openings connected by a channel.

In Fig. 4 (page 4, lines 5-8), raised edge 6 and indentations 7 cooperate to insure attachment of the cartridge/cassette 1. Similar action is provided by indentation 8 and button 9 of Fig. 5 (page 4, lines 9-14).

After the cap/cover 5 has been attached, the cartridge/cassette may be placed on a photocopier for photocopying of the test results showing in window 2.

(6) ISSUES

The issues presented for review are:

Issue 1. Are claims 1, 8, 23-34 and 37-48 rejectable under 35 USC 103(a) as being unpatentable over Dafforn et al. (US 4,981,786) in view of Senior (US 5,504,013)?

Issue 2. Are claims 1, 8, 23-48 rejectable under 35 USC 103(a) as being unpatentable over Chipkowski (US 5,976,895) and WO (WO 97/33519) alone or in view of Senior?

(7) GROUPING OF CLAIMS

For the ground of rejection corresponding to Issue 1, claims 1, 8, 23-34 and 37-48 do not stand or fall together.

For the ground of rejection corresponding to Issue 2, claims 1, 8, and 23-48 do not stand or fall together.

(8) ARGUMENT

Issues 1 and 2 - Introduction

The rejections are all on the basis of obviousness under 35 USC 103(a). With reference to MPEP Section 2142, three basic criteria must be satisfied, in order to have a valid prima facie obviousness rejection:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there

must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Relative to the third criterion, the references contain no teaching nor suggestion of the snap connections of claims 37 and 38 and the photocopying of claim 41. Applicants have requested citations numerous times, examples being: AMENDMENT filed 10/11/02, page 5, lines 13-15; and AMENDMENT filed 10/15/01, page 5, lines 2-4, and page 6, lines 7-11. While applicants acknowledge that snap connections and photocopying are known to mankind, the first criterion is not satisfied in this instance without appropriate citations for these features. Without citations, there is no basis upon which to judge whether there is motivation or suggestion for the proposed modifications of the primary references. Applicants also note that, if applicants traverse an assertion of official notice, the examiner should cite references; see MPEP Section 2144.03.

If prima facie obviousness is established, such may be rebutted on the basis of secondary considerations, such as commercial success. MPEP Section 2141. A declaration of commercial success was filed 10/15/01.

The rejections of the claims are analyzed on the basis of the three criteria as follows.

Issue 1 - Claims 1,8,23-34 and 37-48

Dafforn has sample wells, such as items 20 and 22 on the bibliographic page of the patent. Dafforn expresses no concern for sample getting out of these wells.

Dafforn does want the sample opening to have good contact with the test strip to get complete absorption. Dafforn, col. 13, lines 14-18. That is at a location down inside Dafforn's housing. Presumably, otherwise sample might escape internally, into the housing spaces beneath the test strip. Thus, Dafforn's bibulous test strip is recessed within the sample opening and contained within the housing, whereas the illustrated bibulous member 16 in Senior protrudes out of the housing.

Dafforn does not disclose any need for turning its device over, such as for photocopying as in the present disclosure. Line 1 of Dafforn's col. 14 says that a scale may be provided on the face of the device to assist in quantitating.

Senior displays a protruding, exposed bibulous member 16 which is intended to be soaked from a urine stream (see claim 7 of Senior). It is clear that there should be concern for shielding with a cap in such a case.

Dafforn, in contrast, does not have a protruding, exposed bibulous member. Rather, Dafforn's bibulous strip is hidden within its housing. And, Dafforn is not concerned with the application of the massive amounts of sample indicated by Senior's reference to a stream of urine, but, instead, like the present

invention, deals with quantities measured in drops (see: Dafforn, col. 13, line 34; present specification, page 3, lines 18 and 19; and applicant's DECLARATION UNDER 37 CFR 1.132 filed 8/25/00).

On the basis of these considerations, there is no suggestion or motivation present in the rejection which would have made the proposed modification of Dafforn on the basis of Senior obvious to one of ordinary skill in the art, in order to meet the provisions of claims 1,8,23-34 and 37-48 on the sealing of a sample well.

The claims will now be considered individually as follows.

Issue 1 - Claim 1

Claim 1 specifies that the cap/cover seals the top of the well/opening in a fluid tight relationship. In Senior, the opening is in the end of portion 13. Member 16 protrudes out of the opening. When cap 15 is in place, sample can still move out of the top of the opening, into the protruding member 16. In Senior, to the extent that there may be a sealing action performed by Senior's cap 15, it appears to be along the sides of extended portion 13, rather than at the top of the opening. However, there is no exact specification in Senior of where a sealing action is located between the cap 15 and the extended portion 13 or casing 10.

Senior is like placing a tent over the area of concern, while the rejected claims require a positive sealing of the top of an opening or well. The present inventors have exercised ingenuity

to see that a cap applied as in Senior will result in a direct closing off of a well/opening as in Dafforn, rather than having a situation as in Senior where urine is free to leave the opening. That realization comes from the present inventors, rather than from Senior's teachings.

Of course, it has been pointed out that Dafforn uses only very small quantities of sample, whereas Senior uses relatively immense quantities. But, if that barrier to the transfer of the ideas of Senior into Dafforn might somehow be overcome, there would still remain the question of how Senior's "tenting" of a protruding bibulous member might be applied in Dafforn. One of ordinary skill, thinking analogously to what was done in Senior, might provide a cap to go around the outer side walls of Dafforn's housing 12 to enclose wells 20,22, like a lid one puts over a seed pot, when trying to get seeds to germinate at the end of winter. That would put a tent over the wells, but it would not seal the tops of the wells, as required in claim 1.

Paragraph a. in col. 5 of Senior has been noted, but this does not inherently lead to a structure where the cap seals the top of the aperture. For instance, said paragraph a. could be accomplished by cutting member 16 off flush with the end of portion 13. This would not change the fact that sample could still move out of Senior's opening, into the interior of cap 15

and that any sealing appears to be along the sides of extended portion 13.

The feature of a sealed top is naturally also present in dependent claims 23-34, 37-41, and 45-48.

Issue 1 - Claim 8

Independent claim 8 adds over claim 1 the specification of a drug screening device in the preamble and a drug test strip in the body of the claim. While Dafforn may, or may not, disclose those extra features, if it does, such would have been an additional obstacle for application of the teachings of Senior into such an environment, because Senior does not disclose either a drug screening device or a drug test strip, and instead mentions pregnancy testing (Senior col. 1, line 8, and col. 2, line 54).

Issue 1 - Claim 23

This claim is for a method of using the assaying device of claim 1 and includes steps of depositing the sample into the well/opening (the example disclosed is dropping sample from a pipette) and attaching the cap/cover means to seal the top of the well/opening in a fluid tight relationship. Dafforn lacks the attaching step. Senior does not seal the top of the opening in the end of extended portion 13.

Issue 1 - Claim 24

This claim provides that there is a sample-receiving space extending into the cartridge/cassette means from the top of the

well/opening. While Dafforn discloses this feature, and Senior's col. 1, line 52, col. 4, line 16, and col. 5, line 30, may indicate that its bibulous member has some extent from the opening of extension 13 into its interior, Senior does not disclose the association of a sealable top and a sample-receiving space extending inwards therefrom, as required by this claim 24, through its dependence on claim 1. Consequently, it would not have been clear for one of ordinary skill in the art how a cap as used in Senior could be applied in Dafforn. There is no protruding bibulous member in Dafforn corresponding to member 16 in Senior. Thus, one must be careful not to use the hindsight of the way in which a cap seals a well in the present invention to come to the conclusion that Senior teaches that as a modification of Dafforn.

Issue 1 - Claim 25

Claim 25 specifies that the space defined in claim 24 is empty. While this is the case in Dafforn, it is certainly not the case in Senior. In Senior, bibulous member 16 fills the opening in the end of extended portion 13 in Senior. Paragraph a. in col. 5 of Senior does not inherently disclose a structure meeting the feature of claim 25, because paragraph a. could be accomplished by cutting member 16 off flush with the end of portion 13. While Senior teaches how to use a cap to shield a wet, protruding, bibulous member, the bibulous member in Dafforn is wholly contained within the housing, so that one of ordinary skill would

not have conceived of any need for the cap of Senior on the device of Dafforn.

Issue 1 - Claim 26

In contrast to the sealed chamber of this claim extending from the top of the well/opening into the cartridge/cassette, Senior teaches having urine in its cap outside of the top of its opening. So, applying Senior to Dafforn, one of ordinary skill might, for the sake of argument, come to, say, a plastic dome over the wells 20,22 of Dafforn, but not to the transforming of said space into a chamber for retention of sample, as claimed in claim 26.

Issue 1 - Claim 27

This claim relates to placing the well/opening such that it can face upwards in a most stable orientation of the cartridge/cassette. The cartridge/cassette is then especially resistant against tipping when and after the pipette is brought into position for deposit of sample. While Dafforn discloses this feature, Senior does not. Rather, Senior places its opening on the end of its extension 13. Urine can drip or spill from the bibulous member onto objects below, such as a table or floor, and onto the interior surface of the cap, once the cap is in place. The location on extension 13 of the one or more apertures mentioned in paragraph a. of col. 5 of Senior is not disclosed by Senior, other than the aperture shown in Senior's drawings in the

end of 13. Given the protrusion of the bulbous member 16 in Senior and the copious application of urine thereto, it is natural to expect subsequent covering of the protruding member with a cap, so that dripping and contact with other objects is avoided. In contrast, in the case of Dafforn, there would have appeared to be no need of a cap in the eyes of one of ordinary skill.

Issue 1 - Claims 28 and 29

These claims are directed to the features that the cap/cover means passes around or completely encircles the cartridge/cassette, in order to hold a fluid tight seal. The exact location of the possible seal discussed in Senior beginning at col. 2, line 33 is not disclosed. Neither does Senior show the combined interaction between the top of the sample well/opening and the cap/cover means resulting from the dependence of claims 28 and 29 on claim 27. If one of ordinary skill would keep the orientation of Senior's cap relative to the opening in the end of its extension 13, in transferring to Dafforn, the structural features of passing around (claim 28), or encircling (claim 29), coupled with fluid tight relationship against the top, would not exist in Dafforn.

Issue 1 - Claims 30-32

Claims 30-32 correspond to claims 24-26 and combine the specially oriented well/opening of claim 27 with the features of a sample-receiving space inwards of the sealable top, the empty

space, and the sample-retaining chamber. Senior's opening is not so specially oriented, nor does it disclose the cooperation between the sealable top and the inwards lying sample space, nor does it disclose an empty space or a sample-retaining chamber inwards of the sealed top. Given the way Senior's cap is associated with the opening in the end of its extension 13, and assuming for the sake of argument that one of ordinary skill would even think of applying a cap to Dafforn, such a cap would be more apt to sit like a dome above wells 20,22, with the sides of the cap encircling the lateral sides of Dafforn's housing 12. This would not seal the tops of wells 20,22, as required by these claims.

Issue 1 - Claims 33 and 34

These claims correspond to claims 28 and 29 but depend from claim 32, in order to group together the features of the specially oriented well/opening of claim 27, the empty space, and the sample-retaining chamber with the features that the cap/cover means passes around or completely encircles the cartridge/cassette, in order to hold a fluid tight seal. The exact location of the possible seal discussed in Senior beginning at col. 2, line 33 is not disclosed, but, with Senior's opening being on the end of 13, Senior certainly does not disclose the sealing of the top of a well/opening on the broad lateral face of

its extension 13. Furthermore, if the cap-to-opening relationship of Senior were applied in Dafforn, there would be no sealing of the tops of Dafforn's wells 20/22.

Issue 1 - Claims 37 and 38

These claims specify snap fits. Senior, in contrast, discloses a telescoping fit (see e.g. Senior, col. 4, line 12). The examiner was asked to supply a suitable reference to supply the lack in Senior, but no such reference has been included in the rejection.

Issue 1 - Claims 39 and 40

These claim the dropping of sample, for instance with a pipette, into the well, and then the attaching of a cover to seal the well. It is precisely this combination of features which would not have been obvious on the basis of Dafforn and Senior, because it requires the insight of the present inventors that something from the large liquid quantity world of Senior might have use for the small liquid quantity world of Dafforn.

These claims additionally specify the sealing of the top of the well, a feature which also would not have been obvious, since Senior does not do that.

Issue 1 - Claim 41

In this claim, once the cap is attached, a photocopying of the test results is performed. Photocopying is in neither Dafforn

nor Senior. The examiner was asked to supply a secondary reference, but has chosen not to do so.

Issue 1 - Claim 42

This claim first sets forth that the assaying device combines a broad, lateral face with two narrow faces. Then, it places the sample deposit well in the broad, lateral face. Only "well" is used in claim 42, rather than "well/opening", since "well" better conveys the idea of the presence of a pocket, or depression, such as is visible, for instance, in Fig. 1 of the drawings, numeral 4b. The setting is much like that shown in Dafforn.

This then is coupled with language from the bottom of page 3 of the specification, that a cap/cover is provided to cover and seal the well in a fluid tight relationship, following deposit of the sample.

Comparing claim 42 to Senior, Senior in contrast has its sample-collecting opening in a narrow end face, and the opening has member 16 filling and protruding out of it, rather than being in the nature of a well with a vacant space in its upper part.

Given the very different structural setting in Senior, it would not have been obvious for one of ordinary skill in the art to introduce the cap of Senior into the setting of Dafforn.

Issue 1 - Claims 43 and 44

The patent of Senior concerns a fundamentally different technology from that forming the basis for the present invention.

A declaration of the third joint inventor, Gary Hoffman, under 37 CFR 1.132 was presented with the AMENDMENT of 8/25/00 to explain this different technology referenced in the BACKGROUND of the specification. It is unclear whether Dafforn discloses this technology. Only three drops of urine are applied, compared with the massive soaking used in Senior. Claims 43 and 44 were added to present alternative claims specifying the presence of this different technology.

Claim 43 is presented in the format provided in 37 CFR 75(e). The preamble specifies the environment in which the later specified improvement exists. The wording for the preamble incorporates the different technology as compared to Senior, by specifying "a test strip for the immunoassay method called antigen-antibody competitive binding to test a urine sample for drug use" Senior, in contrast, cites pregnancy testing. The preamble also places the well in the broad, lateral face, as described above for claim 42, as shown in Dafforn, this in contrast to Senior's placing the sample-receiving orifice in its narrow end face. Given these differences, it would have been unclear to one of ordinary skill how one might apply Senior to Dafforn.

Claim 44 brings out the process differences. Urine is dropped into a well and the well then covered, in a drug test. In Senior, the idea appears to be to have a patient urinate onto a

protruding bibulous member and then cover the protruding member with a cap. It was beyond ordinary skill to apply the cap from a situation where the patent urinates on a protruding, bibulous member, to the very different environment of Dafforn, where urine is added dropwise into a sample well.

Issue 1 - Claim 45

Claim 45 further distinguishes over the situation in Senior for modifying Dafforn. Thus, in Senior, the sample opening is on an end, and the wall of Senior's cap facing that end is not a wall which contacts the top of the sample opening. In contrast, claim 45 specifies that the very wall facing the surface containing the opening does contact the top of the opening. One of ordinary skill in the art would not have viewed Senior as applicable for modifying Dafforn in this way.

Thus, in Senior, one sees a soaked bibulous tongue 16 sticking outwards, and a cap 16 goes over that tongue. In Dafforn, considering its embodiment of Figs. 10-13, which is the only embodiment of Dafforn illustrating a window 262 like applicant's window 2, bibulous member 214 is internal and sample is supplied to bibulous member 214 through two small holes in the bottoms of wells 220,2. To come to the invention defined in claim 45, one has to conceive of the idea of sliding a cap, for the most part, onto a housing end, not over a protruding, wet tongue. Only coincidentally might that cap seal wells 220,2. The situation is

sufficiently different that such a modification of Dafforn would have been beyond ordinary skill in the art for this reason also, quite apart from the fact that Dafforn only deals with drop-quantities of sample, as brought out above.

Additionally in support of the non-obviousness of the invention defined in claim 45, it is noted that a markedly different type of sealing is achieved in the present invention, as compared to the sealing in Senior. In Senior, urine is free to move beyond the seal into the cap, whereas, in the present invention, a wall of the cap, in sealing, contacts the top of the well/opening, so that urine is not free to move beyond the seal into the cap.

Issue 1 - Claim 46

When one considers that in both Dafforn and the present invention, the top parts of the wells are even vacant, modification on the basis of Senior's disclosure of protecting a protruding wet tongue was even more remote for one of ordinary skill. Claim 46 states the existence of this situation of a vacant upper part of the well in combination with claim 45.

Issue 1 - Claim 47

Claim 47, which depends from claim 46, specifies applicant's preferred test strip. Dafforn does not use the word "competitive" and Senior is testing for pregnancy, not drugs. See Senior e.g. col 2, line 54.

Issue 1 - Claim 48

This claim specifies the important measured adding of test sample - see paragraph 8. of applicant's DECLARATION UNDER 37 CFR 1.132 filed 08/25/00. As indicated in said paragraph 8, the arts of Dafforn and Senior are different in that one uses very small quantities of sample, while the other uses a flooding of sample. It went beyond ordinary skill in the art to conceive of applying a cap obviously needed in the wet environment of Senior into the comparatively dry environment of Dafforn.

Issue 2 - Claims 1,8 and 23-48

The rejection without Senior is based on reading the container 11 of Chipkowski and WO on the cap/cover means of claims 1,8 and 23-48. Then the cartridge/cassette means of these claims would be the test cards of WO and Chipkowski, with their openings 51. See Fig. 9 in WO and Fig. 10 in Chipkowski. All of claims 1,8 and 23-48 require a fluid tight sealing of a well/opening, yet there is no such sealing of openings 51 of the test cards in Chipkowski and WO; see, for instance, the gap on the left and right sides of card 25 as it passes through insert 15 in Fig. 1 of Chipkowski, and the rejection of sealing implied by the discussion of the prior art at col. 1, line 47, in Chipkowski and at page 3, line 7, in WO. There is no suggestion or motivation in Chipkowski and WO for sealing either; their solution is a container 11 that stays upright during the test. These references teach, for

instance, against allowing urine beyond the max. lines on the test cards (see the max. lines on the referenced Figs. 9 and 10).

As to the rejection on Chipkowski and WO adding Senior, the only time that Chipkowski and WO gets sealed is when the solid cap 23 is applied to the container 11. But then the test card, corresponding to the present cassette, is first removed! See WO, page 5, lines 5-18. Similar disclosure is in Chipkowski, col. 2, line 32.

To apply Senior, one of ordinary skill in the art would have had two choices: 1) modify container 11 to provide a fluid tight seal; or 2) apply a cap as in Senior after the test card is removed.

There is no motivation for the first choice, because one of ordinary skill would have considered the container 11 and its manner of use to be adequate for achieving the basic necessity of Cipkowski and WO, as it is stated in Cipkowski at col. 1, lines 22-24 and in WO at page 2, lines 8-10.

In the case of the second choice, such is not suggested either. First, there is no teaching in Cipkowski and WO of what happens to the removed card. It might as well be placed in the waste, because the test using it is done. Additionally, there would be wet urine on the card itself, not just on the internal test strips, and it is not taught how this external urine could be contained by a cap of Senior.

The claims will now be considered as to their individual features as follows.

Issue 2 - Claims 1 and 8

These claims define a well/opening having a top. This top is discussed in the present specification, in the insertion for line 19 on page 3, where it is stated that the well/opening has a top in the area of top edge 4a (see Fig. 1 of the present drawings). The claims further specify that there is a cap/cover means which seals this top in a fluid tight relationship following deposit of the sample.

In Cipkowski and WO, there is no sealing of the tops of the sample openings 51. It furthermore would not have been obvious to provide a sealing. The openings 51 are intentionally exposed to a urine bath during testing.

And, even Senior does not disclose sealing the top of its opening in the end of its portion 13. In Senior, to the extent that there may be a sealing action performed by Senior's cap 15, it appears to be along the sides of extended portion 13, rather than at the top of the opening. However, there is no exact specification in Senior of where a sealing action is located between the cap 15 and the extended portion 13 or casing 10.

The feature of a sealed top is present in all of claims 23-41 and 45-48 depending from claim 1.

Issue 2 - Claim 23

Cipkowsky and WO describe the drug test as involving putting a certain amount of urine in container 11 and then inserting the test card down into the urine (see middle of col. 4 in Cipkowsky and page 10 in WO). There is no subsequent attaching of container 11 to seal the tops of the openings 51. The test results are read through the wall of the container 11. After that, the card is removed, if the urine plus container is to be shipped for further testing. There is no discussion in Cipkowsky and WO on what happens otherwise, whether the unit of container plus card is tossed into a waste receptacle, or whether the card itself is tossed, of the urine is being shipped.

If the card were removed and a cap of Senior somehow applied, it would be messy, because the entire card was previously in urine. Use of Senior's cap in such a situation is not suggested either by Cipkowsky and WO or by Senior.

Issue 2 - Claims 24 and 30

These claims provide that there is a sample-receiving space extending into the cartridge/cassette means from the top of the well/opening. While Cipkowsky and WO disclose this feature, they certainly have no suggestion for sealing the top around such a space.

Senior's col. 1, line 52, col. 4, line 16, and col. 5, line 30, may indicate that its bibulous member has some extent from the opening of extension 13 into its interior, but Senior does not

disclose the association of a sealable top and a sample-receiving space extending inwards therefrom, as required by these claims, through their dependence on claim 1. Consequently, it would not at all have been clear for one of ordinary skill in the art how a cap as used in Senior could be applied in Cipkowski and WO. There is no protruding bibulous member in Cipkowski and WO corresponding to member 16 in Senior. Thus, one must be careful not to use the hindsight of the way in which a cap seals a well in the present invention to come to the conclusion that Senior teaches that as a modification of Cipkowski and WO.

Claim 30 differs from claim 24 by depending from claim 27. While Cipkowski and WO show the feature of claim 27, the inclusion of that feature with that of claim 30 would have increased the difficulty for one of ordinary skill in the art of figuring out how Senior might apply, because Senior's opening is located on the narrow end face of Senior's extension 13, not the broad, top face.

Issue 2 - Claims 25,31 and 46

These claims require an empty space. While this is the case in Cipkowski and WO, there is no suggestion in these references for sealing the top around such a space. Instead, the spaces 51 stay open to the urine in the container.

In Senior, there is no empty space. Rather, bibulous member 16 fills the opening in the end of extended portion 13 in Senior. Paragraph a. in col. 5 of Senior does not inherently disclose a

structure meeting the feature of these claims, because paragraph a. could be accomplished by cutting member 16 off flush with the end of portion 13. While Senior teaches how to use a cap to shield a wet, protruding, bibulous member, there is nothing protruding out of openings 51 in Cipkowsky and WO. One of ordinary skill would not have conceived of any need for the cap of Senior on the device of Cipkowsky and WO.

Claim 31 differs like claim 30 discussed in the previous section, making the invention of claim 31 even more unobvious than claim 25. Claim 46 depends from claim 45 and is therefore additionally unobvious for the reasons discussed for claims 45 below.

Issue 2 - Claims 26 and 32

In Cipkowsky and WO, container 11 does not seal the top of any of the openings 51 to transform the space in an opening 51 into a chamber for retaining sample. Furthermore, use of a Senior-like cap would not have obvious to one of ordinary skill. There is no discussion in Cipkowsky and WO about what is done with the test card 25 after it is removed (Cipkowsky, col. 4, line 63; WO page 5, line 8) for shipping of the urine to a central lab. The card is probably thrown in the waste. If one would think of putting a Senior-like cap on the card, the urine clinging to the outside of the card would lead to urine on the outside of the cap.

Claim 32 differs like claims 30 and 31 discussed in the previous sections, making the invention of claim 32 even more unobvious than claim 26.

Issue 2 - Claims 27-34 and 42-44

While Cipkowsky and WO do show opening 51 in a broad, lateral face, Senior's opening is in a narrow, end face, so that the question exists here also, as in the case of Dafforn, as to how Senior's teachings might be applied in Cipkowsky and WO. For instance, Senior would seem to suggest a bubble over the openings 51, rather than a cap sliding over them. Of course, here too, there are additional difficulties with applying Senior, such as the urine on the test card 25 and the lack of any teaching for retention of the test card following the test.

Issue 2 - Claims 28,29,33 and 34

Container 11 in Cipkowsky and WO does not pass around or encircle test card 25 in order to hold container 11 in a fluid tight relationship against the top of opening 51. And, as explained above, there is no motivation for using Senior's cap in Cipkowsky and WO. For instance, when test card 25 is removed, there is no reason indicated in Cipkowsky and WO for retaining it, and, in any event, use of Senior's cap would lead to urine on the outside, since the entire test card was earlier in a urine bath.

Issue 2 - Claim 35

While Cipkowski and WO shows multiple test strips, none of the tops of openings 51 are sealed in a fluid tight relationship, as required by this claim. There is, furthermore, no motivation in Cipkowski and WO for modifying Cipkowski and WO in this manner. Their test presupposes immersion in a urine bath. Senior only deals with one test strip and additionally is inapplicable for reasons given above, such as urine on the outside of the test card and no teaching concerning retaining the test card following the test.

Issue 2 - Claim 36

There is no channel, as in the present Fig. 3, interconnecting openings 51 in Cipkowski and WO. Senior does not help in this regard either.

Issue 2 - Claims 37 and 38

There are no snap fittings in Cipkowski and WO between test card 25 and container 11, nor are there any in Senior either. Applicant challenged the examiner's assertion that such is within the skill of the art and requested a reference be applied. And, there are affirmative reasons why snap fittings are not indicated in Cipkowski and WO and in Senior. In Cipkowski and WO, adjustability up and down should be maintained, to retain the max. level line in the case of more and less urine in container 11, and in Senior, a telescoping fit is needed, so that the cap can be changed from one side to the other during use.

As between claims 37 and 38, there are differences in structural details between these claims. In contrast, the rejection is based on a mere allegation by the examiner that "snap fit is within the skill of the art. See the final action of 12/05/02, bottom of page 3, just before the heading "Conclusion."

Issue 2 - Claims 39, 40, 44 and 48

Both in the case of Cipkowski and WO and in the case of Senior, the sample receiving areas are flooded with urine, in contrast to dropping the sample, for instance using a pipette, as required by these claims. Additionally, there is no motivation in any of these references Cipkowski, WO and Senior, for a change from this practice of flooding.

As between these claims, claims 39 and 40 require the feature of claim 27, which increases the difficulty of proving obviousness utilizing Senior's opening on the narrow end face of extension 13. Claim 44 adds that the test is for drug use, so it's a drug use test involving dropping of urine, rather than flooding as in Cipkowski and WO, while Senior involves a urine flooding test for pregnancy; there is no motivation for changing the flooding procedures in any of Cipkowski, WO or Senior, and Senior presents the additional difficulty of its involving not a drug test, but a pregnancy test. Claim 48, by its dependence from claim 45, adds the feature that the cap wall facing the face containing the well contacts the top of the well, which is not the case in Senior, as

brought out in the discussion of claim 45 below, thus increasing the unobviousness of the total combination of features presented in claim 48.

Issue 2 - Claim 41

There is no disclosure of the method step of photocopying the test results in any of Cipkowski, WO and Senior. Furthermore, none of these references contain any suggestion for such. Applicant challenged the examiner's assertion that such is within the skill of the art and requested citation of a reference.

Issue 2 - Claim 45

As indicated above, when applying Cipkowski and WO alone, the examiner asserts that the container 11 of these references corresponds to the cap/cover of this claim. However, in Cipkowski and WO, the wall of the container 11 which faces the face of the test card 25 having openings 51 is spaced from that face, instead of contacting the tops of openings 51, as required by this claim. Likewise in Senior, the wall of Senior's cap 15, which faces the end face of Senior containing the opening, is spaced from that face. So, no reference in this rejection shows the structural feature of this claim, that a wall of the cap/cover means faces the face containing the well/opening and contacts the top of the well/opening for sealing.

Conclusion

For the reasons given, the rejections associated with Issues 1 and 2 are not well founded. Reversal of the rejections of all appealed claims 1,8 and 23-48 is in order and is requested.

Respectfully submitted,



Daniel A. Sullivan Jr.
Attorney for the Applicant
Reg. No. 25068
Telephone No. (724) 335-1331

(9) APPENDIX I

A copy of the claims involved in the appeal follows:

1. An assaying device for depositing and analyzing a sample, comprising:

a. a cartridge/cassette means which contains a test strip, a window for viewing test results and a well/opening separate from the window, having a top and serving for deposit of the sample; and

b. a cap/cover means for sealing the top of the sample well/opening in a fluid tight relationship following deposit of the sample.

8. A drug screening device for depositing and analyzing a urine sample, comprising:

a. a cartridge/cassette means which contains a drug test strip, a window for viewing test results and a well/opening separate from the window, having a top and serving for deposit of the urine sample; and

b. a cap/cover means for sealing the top of the sample well/opening in a fluid tight relationship following deposit of the sample.

23. A method of using an assaying device as claimed in claim 1, comprising the steps of: depositing the sample into the well/opening; and attaching the cap/cover means to cover and seal the top of the well/opening in a fluid tight relationship.

24. An assaying device as claimed in claim 1, the well/opening extending from its top into the cartridge/cassette means to surround a space for reception of sample.

25. An assaying device as claimed in claim 24, the space being empty.

26. An assaying device as claimed in claim 25, the cap/cover means when sealing the top of the sample well/opening transforming said space into a chamber for retention of sample.

27. An assaying device as claimed in claim 1, the well/opening being situated on a broad, lateral face of the cartridge/cassette means.

28. An assaying device as claimed in claim 27, the cap/cover means when sealing the top of the sample well/opening passing around the cartridge/cassette means, in order to hold the cap/cover means in a fluid tight relationship against the top of the sample well/opening.

29. An assaying device as claimed in claim 28, the cap/cover means when sealing the top of the sample well/opening completely encircling the cartridge/cassette means, in order to hold the cap/cover means in a fluid tight relationship against the top of the sample well/opening.

30. An assaying device as claimed in claim 27, the well/opening extending from its top into the cartridge/cassette means to surround a space for reception of sample.

31. An assaying device as claimed in claim 30, the space being empty.

32. An assaying device as claimed in claim 31, the cap/cover means when sealing the top of the sample well/opening transforming said space into a chamber for retention of sample.

33. An assaying device as claimed in claim 32, the cap/cover means when sealing the top of the sample well/opening passing around the cartridge/cassette means, in order to hold the cap/cover means in a fluid tight relationship against the top of the sample well/opening.

34. An assaying device as claimed in claim 33, the cap/cover means when sealing the top of the sample well/opening completely encircling the cartridge/cassette means, in order to hold the cap/cover means in a fluid tight relationship against the top of the sample well/opening.

35. An assaying device as claimed in claim 1, the cartridge/cassette means containing a second test strip, a second window for viewing test results and a second well/opening having a top and serving for deposit of the sample, whereby there are two well/openings whose tops are sealed by the cap/cover means in a fluid tight relationship following deposit of the sample.

36. An assaying device as claimed in claim 35, said two well/openings being connected by a channel.

37. An assaying device as claimed in claim 1, the cartridge/cassette means having a raised edge and the cap/cover means having indentations, the raised edge and the indentations, when snapped together, insuring the attachment of the cartridge/cassette means with the cap/cover means.

38. An assaying device as claimed in claim 1, the cartridge/cassette means having an indentation and the cap/cover means having a raised button, the indentation and button, when snapped together, insuring the attachment of the cartridge/cassette means with the cap/cover means.

39. A method of using an assaying device as claimed in claim 31, comprising the steps of: dropping the sample in the form of urine into the well/opening; and attaching the cap/cover means to cover and seal the top of the well/opening in a fluid tight relationship.

40. A method as claimed in claim 39, wherein the dropping is done from a pipette.

41. A method as claimed in claim 23, further comprising, following the step of attaching, the additional steps of placing the cartridge/cassette on a photocopier and photocopying test results showing in the window.

42. An assaying device for depositing and analyzing a sample, comprising:

I. a cartridge/cassette having a broad, lateral face (1a), a narrow, lateral face (1b), and a narrow end face (1c);

A. the cartridge/cassette containing a test strip, a window in the broad, lateral face for viewing test results and, separate from the window, a well in the broad, lateral face to serve for deposit of the sample; and

II. a cap/cover means for covering and sealing the well in a fluid tight relationship following deposit of the sample.

43. In a device, having:

I. a cartridge/cassette having a broad, lateral face (1a), a narrow, lateral face (1b), and a narrow end face (1c);

A. the cartridge/cassette containing

i. a test strip for the immunoassay method called antigen-antibody competitive binding to test a urine sample for drug use,

ii. a window in the broad, lateral face for viewing test results and, separate from the window,

iii. a well in the broad, lateral face to serve for deposit of the sample;

the improvement comprising:

II. a cap/cover means for covering and sealing the well in a fluid tight relationship following deposit of the sample.

44. A method of using a device as claimed in claim 43 to test for drug use, comprising the steps of dropping a urine sample into

the well and then covering and sealing the well with the cap/cover means in a fluid tight relationship.

45. An assaying device as claimed in claim 1, the well/opening being on a face of the cartridge/cassette means, the cap/cover means having a wall which, in sealing, faces said face and contacts the top of the well/opening.

46. An assaying device as claimed in claim 45, the well/opening extending from said top into the cartridge/cassette means to surround an empty space for reception of the sample.

47. An assaying device as claimed in claim 46, the cartridge/cassette means further containing a test strip for the immunoassay method called antigen-antibody competitive binding to test a urine sample for drug use.

48. A method of using a device as claimed in claim 47 to test for drug use, comprising the steps of dropping a urine sample into the well and then covering and sealing the well/opening with the cap/cover means in a fluid tight relationship.

Appendix II - 08/935,629

AN ASSAYING DEVICE CONSISTING OF THE TEST CARTRIDGE OR CASSETTE WITH A CAP OR COVER WHICH ATTACHES ONTO THE CARTRIDGE OR CASSETTE TO COVER AND SEAL THE WELL OR OPENING INTO WHICH THE SAMPLE HAS BEEN DEPOSITED

Spec as filed
Amended 11/16/98
Amended 7/12/99
Amended 10/15/01
Amended 7/22/03

BACKGROUND

This invention generally relates to assaying devices and in particular the on-site immunoassay technology used to detect the presence of drugs in urine. On-site drug tests generally use an immunoassay method called antigen-antibody competitive binding to screen for the presence of drugs. Among the test kits used for such testing there are tests composed of a housing or container which contains a reagent test strip, an opening in which test results are displayed and a place for deposit of the sample. The sample wicks up into the reagent test strip and the results are displayed. The results are generally available within a few minutes. Often it is desirable to make a photocopy of the results, whether positive or negative, for a permanent record, since test results will change or disappear over time.

Possible problems include spilling of the sample, contamination of the sample, and contact by the test administrator or others with the sample during handling. A method is needed for a cleaner, more sanitary and easier handling of the test housing during and after the test administration, especially since specimens can be infectious. In order to photocopy the results, the test device is placed face down on the copier, so it is desirable to insure that sample will not leak onto the copier. Also a method is needed to insure a second sample from another donor is not inadvertently placed in the same test cartridge/cassette.

SUMMARY OF THE INVENTION

The housing or cartridge/cassette of the present invention will have one or two openings or "windows" in which the test results are displayed and one or two wells or openings in the top of the cartridge/cassette for deposit of the sample. The sample is placed in the

well/opening by use of a pipette. The results will be displayed in the window. The cartridge/cassette and the cap or cover of the present invention will prevent the sample used in the test from spilling out, will prevent contamination of the sample, and will permit cleaner, more sanitary and easier handling of the cartridge/cassette during and after the

5 wicking test process. The cap/cover when placed on the cartridge/cassette will provide a fluid tight relationship. The cartridge/cassette with the cap/cover provide a compact, easy to handle unit. The cap/cover if placed on the cartridge/cassette as soon as the sample begins wicking will prevent inadvertent commingling or intermixing of another sample.

It is the principal object of this invention to provide a convenient, compact, easily
10 managed device for the containment of the sample.

It is also a further objective to provide a means to protect the sample from contamination once placed into the test well/opening.

It is a further objective to provide a means to protect the test administrator from undesirable contact with the sample while handling the test cartridge during the test
15 administration.

It is a further objective to provide a means to protect the test administrator or others from undesirable contact with the sample during subsequent handling of the test cartridge.

It is a further objective of the present invention to provide a means of insuring that while photocopying the test results displayed in the test cartridge/cassette the sample will not
20 leak from the well/opening onto the copier.

It is a further objective of the present invention to provide a means to prevent the test administrator from inadvertently commingling or intermixing a second sample from another donor.

These and other objects of the present invention will become readily apparent upon further
25 review of the following specifications and drawings.

BRIEF DESCRIPTION OF THE DRAWING

In the Drawing:

Figure 1 is a perspective view of the cartridge/cassette and cap/cover separately as seen from the front or top;

5 Figure 2 is a perspective view of the cartridge/cassette and cap/cover snapped or slipped together as seen from the front;

Figure 3 is a perspective view of the cartridge/cassette with two windows and two sample well/openings and the cap/cover separately as seen from the front or top.

Figure 4 is a side view of the cartridge/cassette and of the cap/cover (shown in cross

10 section) showing the addition of edges on the cartridge/cassette and indentations on the cap/cover for further securing the cap/cover.

Figure 5 is a side view of the cartridge/cassette and of the cap/cover (shown in cross section) showing the addition of indentations on the cartridge/cassette and raised buttons on the cap/cover for further securing the cap/cover.

15 DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 is a perspective view of the cartridge/cassette and cap/cover separately as seen from the front or top. The cartridge/cassette 1 contains an opening or window 2 in which the results on the test strip 3 will be displayed. The sample will be dropped into the well/opening 4 by means of a pipette. The cap/cover 5 has not been placed onto the 20 cartridge/cassette yet.

Fig. 2 is a perspective view showing the cartridge/cassette and cap/cover snapped or slipped together. Fig. 2 is a view as seen from the front or top. The cartridge/cassette 1 with the results window 2 has the cap/cover 5 snapped or slipped into place. The sample well/opening, 4 in the other Figures, is now covered and sealed by the cap/cover 5 in a fluid tight relationship.

25

(4)

Fig. 3 shows a cartridge/cassette 1 with two results windows 2, two test strips 3, two sample well/openings with a connecting channel 4 and a separate cap/cover 5. This type of cartridge/cassette will accommodate more separate tests and requires a greater quantity of the sample.

5 Fig. 4 shows a side view of the invention with the side of the cap/cover 5 cut away. The cartridge/cassette 1 is designed with a raised edge 6 and the cap/cover (shown in cross section) with indentations 7 which when snapped together will further insure the attachment.

Fig. 5 shows a side view of the invention with the side of the cap/cover 5 cut away. The
10 cartridge/cassette 1 is designed with an indentation ~~8~~⁸ and the cap/cover (shown in cross section) with a raised button ~~9~~⁹ which when snapped together will further insure the attachment. The end of the cartridge/cassette where the well/opening is located has been reduced in thickness with the result that when the cap/cover is attached it will be flush with the edges of the cassette/cover.

15 What is claimed is new and to be protected as set forth in the appended claims. Obviously although the embodiments described herein are the preferred one, modifications can be made to the shape of the cartridge/cassette and the cap/cover, without departing from the spirit and scope of this invention. The cartridge/cassette and the cap/cover may be formed or molded from any suitable material, usually plastic or other similar material, but
20 the invention should work as well with most drug test materials. The cap is effective if it slips onto the cartridge/cassette snugly enough to insure that it will cover and seal the top of the sample well in a fluid tight relationship and will not detach. Raised buttons or edges can also be incorporated into the design of the cartridge/cassette and cap/cover to further insure that the cap/cover when snapped or slipped into place will not detach from the
25 cartridge/cassette. The number of windows and urine well/openings shown are currently available, but more will not depart from the spirit and scope of this invention.

ABSTRACT

An assaying device composed of a test cartridge/cassette and cap/cover. When attached, the cap/cover ^{SEALS} the top of a sample well/opening on the cartridge/cassette in a fluid tight manner, to protect from contact with and contamination of the tested sample (for example, urine for drug testing), provide easier, cleaner handling of the test cartridge/cassette and prevent intermixing of another sample.

(DT_x Added Pg. 8)

Page 3, line 18, between "will be displayed." and "The sample" insert the sentence --As

(1) viewed in Fig. 1, cartridge/cassette 1 shows a broad, lateral face 1a, a narrow, lateral face 1b, and a narrow end face 1c.--.

(2) Page 3, line 19, between "well/opening 4" and "by means" insert --on lateral face 1a--.

Page 3, line 19, between "of a pipette." and "The cap/cover" cancel the sentence presented in the AMENDMENT of 11/16/98 and substitute therefor the following revised sentence: --Well/opening 4, which is separate from window 2, has a top in the area of top edge 4a and extends from there into the cartridge/cassette to surround empty space 4b for reception of the sample.--.

Delete the paragraph at page 3, line 21 through line 25, as amended 10/15/01, and replace such paragraph with the following:

(4) --Fig. 2 is a perspective view showing the cartridge/cassette and cap/cover snapped or slipped together following deposit of the sample. Fig. 2 is a view as seen from the front or top. The cartridge/cassette 1 with the results window 2 has the cap/cover 5 snapped or slipped into place. The sample well/opening, 4 in the other Figures, is now covered and sealed by the cap/cover 5 in a fluid tight relationship. In sealing, wall 5' of cap/cover 5 faces the face 1a containing the well/opening 4 and contacts the top of the well/opening. By sealing the top of the sample well/opening, the cap/cover 5 transforms space 4b into a chamber for retention of sample while the sample wicks for the test. As indicated by the cap/cover region 5a showing in Fig. 2, when assembled with the cartridge/cassette, the cap/cover passes around, and, in fact, encircles, the cartridge/cassette, in order to hold the cap/cover in a fluid tight relationship against the top of the sample well/opening.--

APPENDIX III - 08/935,629

Drawings filed
Amended 11/16/98
Letter to OD 9/27/02

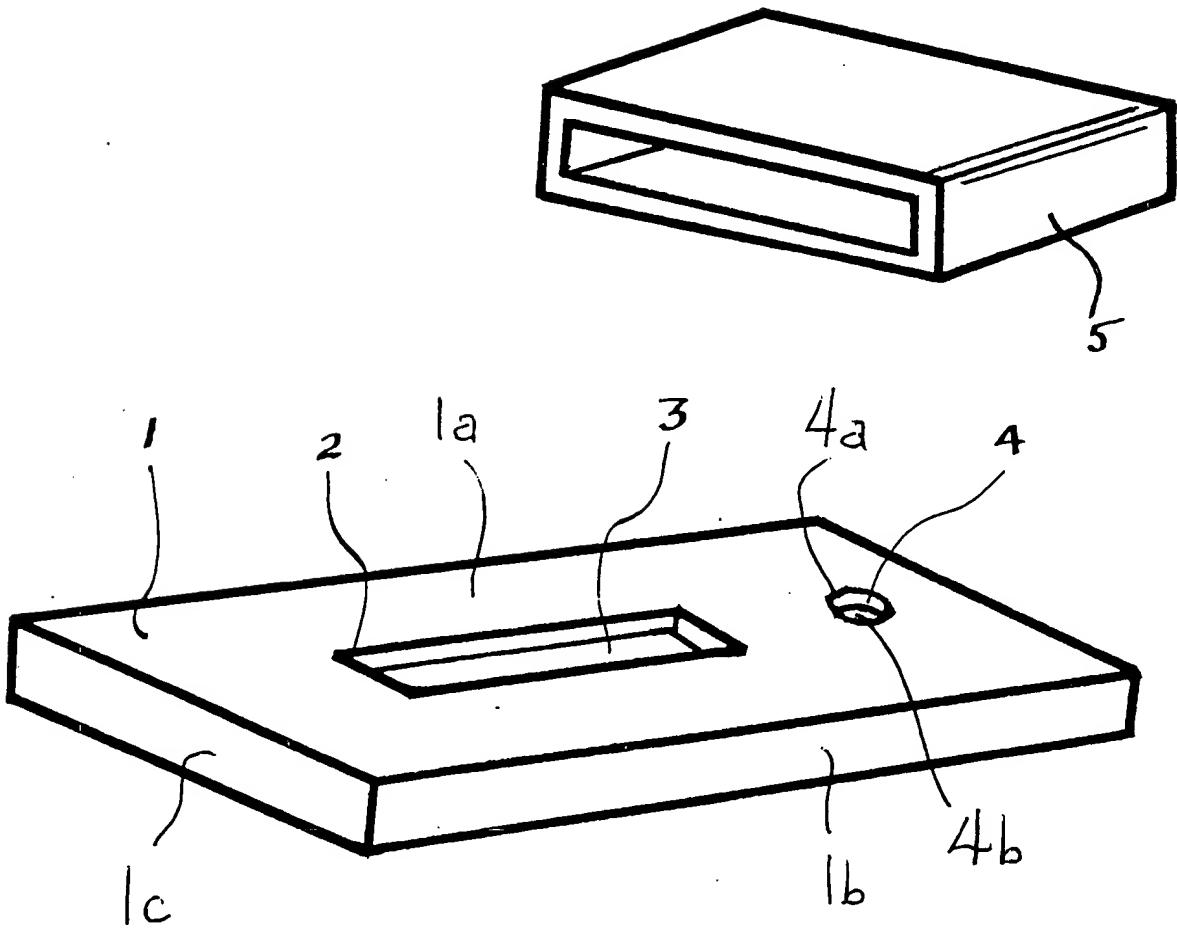


FIG. I

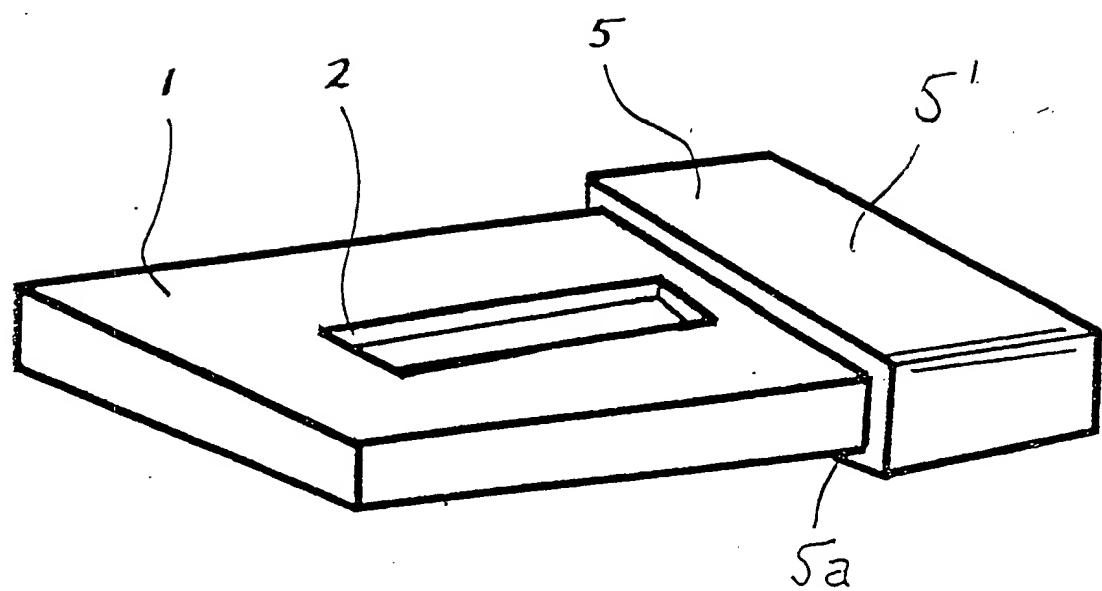


FIG. 2

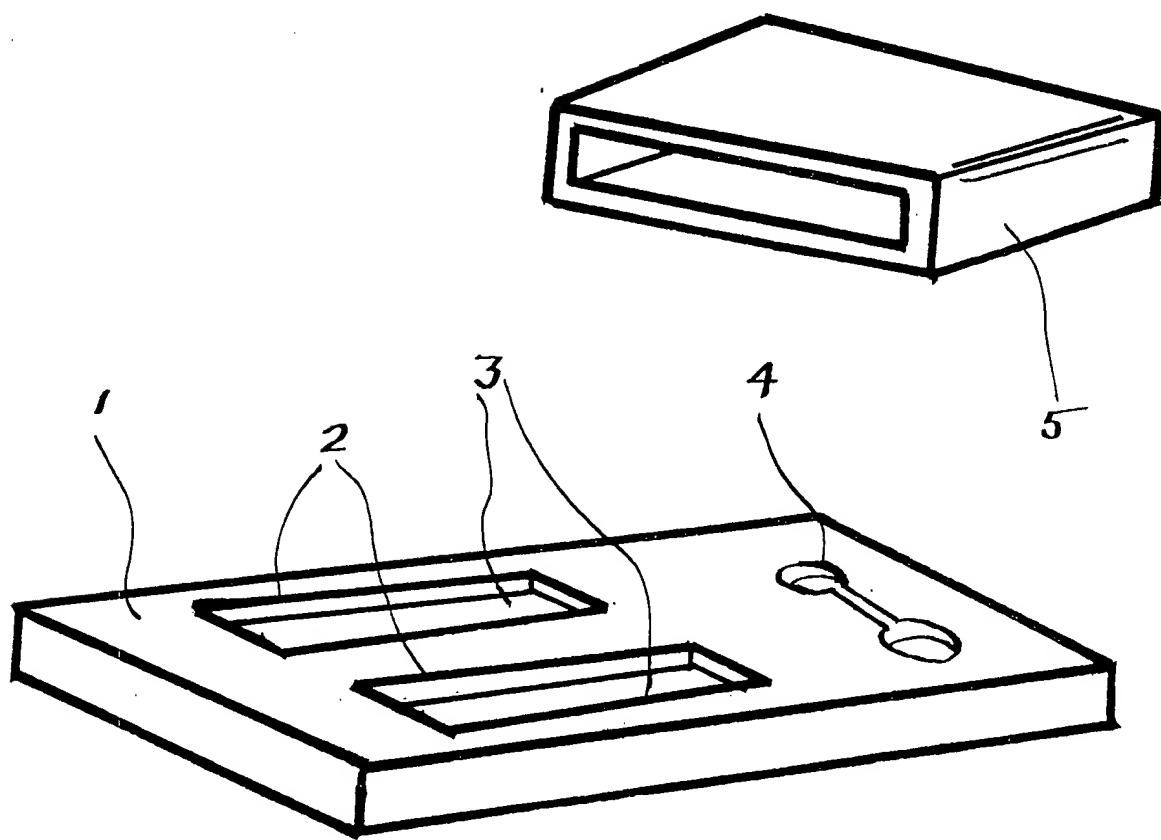


FIG. 3



FIG. 4

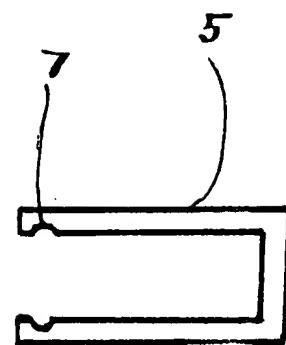
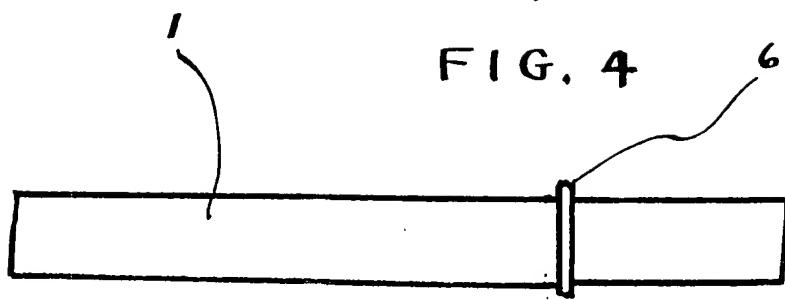


FIG. 5

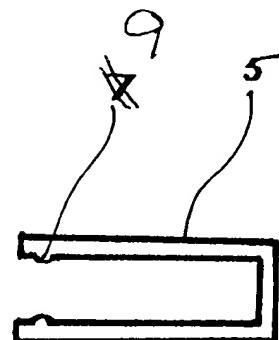
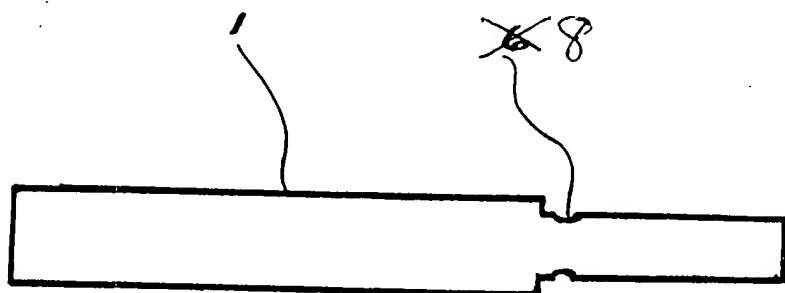


FIG. 5